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PROVISIONAL APPLICATION STATEMENT

This application claims the benefit of the filing date of Provisional Patent Application.

Number 60/274,206 Filing Date 03/09/2001 Title: SafeRite System™

### BACKGROUND OF INVENTION

Medical errors have recently been attributed as a leading cause of death and injury in North America. Many of these medical errors relate to prescription drug mix-ups, such as the patient receiving the wrong drug, or the wrong strength of the right drug etc. Some of these errors are attributed to physician's illegible handwriting, and others to drug selection and dispensing errors in the pharmacy. Other errors result when the drug is administered to the wrong patient in hospital

In response to the issue of sloppy handwriting by physicians some products 9, 10 are coming to market that print an Rx. Generally speaking, these prescriptions are "written" in the physician's office and entail the use of a PDA, (or handheld computer etc.) PC, and office printer.

Although these technologies print a clearly legible Rx 9, 10 – in either hard copy or electronically sent format – they lack design components 3 that prevent pharmacy selection errors. Nor do they provide the patient the means to determine the dispensed drug matches their prescription

### THE 3 PART ACTION PLAN™

In order to prevent medication errors, the following three actions must occur:

- Prevent errors that originate with the physician/writer
- Prevent pharmacy dispensing errors
- Involve the patient

Failure to adopt any one of these actions will result in the ongoing – and unabated – flow of medication errors.

An examination of the PDA/R<sub>x</sub> products (see FIG 11) has found all are uniform in their design approach. Each R<sub>x</sub> met the criteria of part one of the 3 Part Action Plan – that is, the R<sub>x</sub>'s were checked and printed in the physician's office (or sent to the pharmacy electronically) – but lacked the design features necessary to provide other stakeholders in the R<sub>x</sub> loop (the pharmacist, nurse and patient) a comprehensive R<sub>x</sub> safety platform. Other than providing a legible (printed) R<sub>x</sub> to the pharmacist, competing products did not meet the criteria set out in Part Two or Part Three of the 3 Part Action Plan and therefore do nothing to prevent errors occurring in these areas.

\*Autros is a hospital system, designed to deliver dispensed drugs to patients in the ward - but lacks the capabilities of the SafeRite System to prevent drug mix-ups in the hospital pharmacy. Therefore, Autros cannot guarantee the prescribed drug reaches the patient.

## PREVENTABLE MEDICATION ERRORS

### HOW AND WHY THEY HAPPEN

#### IN THE AMBULATORY CARE SETTING

Medication errors can be divided into two main categories and occur when:

Prescriptions are Written	Prescriptions are Dispensed
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#### Rx WRITING ERRORS

The following errors occur at the time the prescription is written:

- Wrong Drug
  - The selected drug is inappropriate for the patient's medical condition
- Strength
  - The correct drug – but wrong strength
- Instructions
  - The correct drug – but wrong dosage instructions
- Abbreviation
  - The incorrect use of an abbreviation
- Interaction
  - The prescribed drug will interact with (other) current Rx's
- Contraindication
  - Drug not compatible with patients medical condition
- Allergy
  - The patient is allergic to the drug
- Patient's name
  - The wrong patient name is written – sometimes the name of the previous patient
- Verbal Orders
  - Orders given by telephone are a continuing source of errors
- Handwriting
  - The physicians handwriting is illegible or difficult to read

## PHARMACY DISPENSING ERRORS

The following errors occur at the time that the pharmacist fills the prescription.

- Handwriting
  - Illegible - or difficult to read - handwritten prescriptions lead to many dispensing errors
- Verbal Orders
  - Orders received by telephone are often misunderstood.
- Drug Selection
  - The wrong drug is selected
- Look Alike
  - Selection errors occur when drug names look alike
- Sound Alike
  - Selection errors occur because drug names sound alike
- Strength
  - The wrong drug strength is selected
- Instructions
  - Incorrect patient instructions
- Interaction
  - The dispensed drug will interact with (other) current Rx's
- Contraindication
  - Drug not compatible with patients medical condition
- Allergy
  - The patient is allergic to the drug
- Patient Chart
  - Various entry errors and chart mix-ups
- Communication
  - The Rx is given out to the wrong patient
- DIN Number
  - Drug DIN number is confused with look alike DIN number

## IN THE HOSPITAL

Hospital medication errors are divided into three main categories and occur when:

Prescriptions are Written	Prescriptions are Dispensed	Prescriptions are Administered
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In addition to the same prescribing and dispensing errors highlighted under Ambulatory Care, further medication errors occur in the hospital when patient identities are confused, resulting in drug mix-ups (the patient is given someone else's medication).

BRIEF SUMMARY OF THE INVENTION

THE SAFERITE SYSTEM™

The SafeRite System™ provides a state of the art, user friendly, low cost solution to the widespread problem of drug mix-ups. The System enables an error free Rx to progress seamlessly from the physician through the pharmacy to the patient. The System's design is unique and is the only Rx technology to address each of the 3 error prevention criteria outlined in the 3 Part Action Plan (competing products address 1 only).9,10

COMPARING THE EFFICACY OF PDA GENERATED Rx's

Refer to FIG 12

The SafeRite System<sup>TM</sup> consist of two sub-systems:

1. SafeRite<sup>TM</sup> is the hardware/software system used by the physician to 'write', bar code and print – or electronically transmit – the two part Rx.
2. SafeReader<sup>TM</sup> is the hardware/software bar code scanning system used by the pharmacist to prevent drug mix-ups in the pharmacy.

#### HOSPITAL SYSTEM

In addition to the benefits of SafeRite and SafeReader outlined above the hospital system includes a bedside visual display that enables the nurse to determine that the prescribed drug goes to the correct patient.

#### FULLY INTEGRATED

SafeRite's<sup>TM</sup> bar coded Rx is fully integrated with SafeReader's<sup>TM</sup> comparative scanning mechanism – resulting in a unique and highly efficient, error prevention system.

- SafeRite assists the physician to quickly and accurately 'write' and print a prescription. By using a printed prescription format, the SafeRite System<sup>TM</sup> precludes errors associated with illegible handwriting.
- SafeRite prints a bar code – representing the drug's name and strength – on the Rx.
- SafeReader's innovative design enables the pharmacist to quickly carry out a bar code comparison check of the Rx and drug selected from stock. This crucial step prevents pharmacy selection errors.
- Finally, the Patient Checklist portion of the Rx encourages patient participation in the prescription loop by providing the patient an easy to follow sequenced checklist.

- Safety features – incorporated into the Rx – are available at each crucial [decision making] juncture of the Rx loop.
- The efficiencies provided to physicians by the SafeRite System™ will discourage giving verbal Rx orders by telephone.
- The SafeRite™ Rx will conform to all federal and state/provincial requirements.
- Competing Rx. products offer a printed Rx, but do not incorporate a bar code (pharmacy protection) or patient checklist, nor do they offer a visual check for hospital use.

The SafeRite System™ provides end users with a powerful safety technology. Benefits accruing to the end user and health care system are substantial financial paybacks resulting in the cessation of deaths and injuries to patients, together with the professional satisfaction of providing the patient a risk free (medication) environment.

DRAWINGS

FIG 1 Illustration showing the two part SafeRite Rx.

FIG 2 Schematic showing sequence of SafeRite Rx and 3 Part Action Plan

FIG 3 Illustration showing a SafeRite generated Rx in which a Generic substitution takes place. The green bordered label is affixed to Box Four.

FIG 4 Illustration of Green bordered generic label see FIG. 3

FIG 5 Illustration of bar coded label. Label is attached to any [non-SafeRite] Rx. For example: to the reverse side of Rx's shown in FIGS 8 and 9

FIG 6 Schematic of SafeRite/SafeReader sequence of use in Hospital and Clinical settings.

FIG 7 Illustrated bedside visual display for Hospital and Clinical use.

FIG 8 Schematic showing carry case for printer and PDA

FIG 9, 10 Rx samples of competitive computer generated Rx products.

FIG 11 Chart showing Vendors of Hand-held Electronic Prescribing Products

FIG 12 Chart comparing efficacy of PDA generated Rx's.

### DETAILED DESCRIPTION OF INVENTION

The SafeRite System™ consist of two sub-systems:

1. SafeRite™ is the hardware/software system used by the physician to ‘write’, bar code and print – or electronically transmit – the two part Rx. FIG 1, 11
2. SafeReader™ is the hardware/software bar code scanning system used by the pharmacist to prevent drug mix-ups in the pharmacy. 12

### HOSPITAL SYSTEM

In addition to the benefits of SafeRite and SafeReader outlined above, the Hospital System FIG.6 includes a bedside visual display (BVD)17 that enables the nurse to determine that the prescribed drug is administered to the correct patient.

### THE SAFERITE Rx

#### PRESCRIPTION DESIGN

The design of the SafeRite™ Rx involved meeting the following four part criteria:

1. Produce a computer generated (printed) Rx FIG 1
2. Build in safety features and increase content 2, 3, 4
3. \* Involve the patient in a final cross-check of the dispensed drug 4
4. Provide a user-friendly system, requiring minimum Rx input

\* Note: As part of a discussion on how to prevent drug mix-ups – “and make the patient their own best defense” – Michael Cohen, of the ISMP, states: “I think it’s becoming very, very important, for the consumers to be informed about what their medications are for, what the names are, how to take them and what the doses are.” 4

The patient's portion of the SafeRite™ prescription leads the patient through the easy to follow Patient Checklist. 4

### R<sub>x</sub> FEATURES

- Clear, large, easy to read printed R<sub>x</sub> 2, 4
- Bar coded – for pharmacy use 3
- Unique two part design – includes patient checklist 2, 4
- Flexible format – print and/or electronic transmission 11
- Conforms to the “3 Part Action Plan” 2, 3, 4

### BRAND NAME / GENERICS

To prevent generic substitution, the physician must write the appropriate state/provincial statement requirement i.e. *No Substitution* 5 or *Dispense as Written* etc. in the box provided.

### PREVENTING LOOK ALIKE / SOUND ALIKE ERRORS

A simple, effective, low cost method of preventing “look alike/sound alike” medication errors - and other selection errors - while filling the Rx in the pharmacy 12, is by incorporating a bar code – containing the drug's brand name and strength – into the Pharmacist's Print Out portion of the R<sub>x</sub>. 3 The R<sub>x</sub> bar code duplicates the drug's brand name and strength, contained in the bar code appearing on the drug's stock container.

To determine the drug taken from stock matches the R<sub>x</sub>, the pharmacist scans the bar codes appearing on both the R<sub>x</sub> and the drug's stock container 12, an incorrect selection – of the drug or drug strength – is immediately flagged:

Note: Scanning is accomplished by using a handheld scanner or a dedicated scanning unit. The unit facilitates the check by scanning both bar codes more or less simultaneously. The unit's program accepts matching codes, but rejects (flags) non-matching codes. The pharmacist rectifies an error by selecting the correct drug/stock container. Matching bar codes allow the program sequence to continue.

### HOW MANY TABLETS A DAY?

The Rx instruction – take 1 tablet daily with meals – can be thoroughly confusing to some patients. Do they take 1 tablet each day OR 1 tablet with each meal? To remedy this common misunderstanding, an information block is added to the bottom of the Patient's Checklist.

For example, the Rx for Zoloft – take 1 capsule daily with meals – would read: 7

Total number of capsules taken daily = 1

The Rx for Flagyl – take 2 tablets 3 times a day with meals – would read:

Total number of tablets taken daily = 6

While the Rx for Tylenol 3 – take 1 to 2 tablets 4 times a day as needed – would show the daily maximum allowable dosage:

Do not exceed 8 tablets daily

## SYSTEM REQUIREMENTS

### PHYSICIAN'S OFFICE (Part One) SAFERITE<sup>TM</sup> 11

#### HARDWARE

- PDA – MODEM – CRADLE
- PC
- PRINTER

Note: PDA can mean any type of computer. The prescriber can also use the office PC to “write” the Rx.

The PDA communicates with the PC and printer by wireless transmission (or infrared).

#### SOFTWARE

- Prescription software for PDA and PC
- PDA/PC interface software

#### SEQUENCE OF USE

The physician calls up the patient's name/file, from the office PC, on their PDA. 11

- Using their PDA the physician enters the reason for treatment – ie depression 10 – and is given a menu of appropriate drugs, then electronically “writes” the prescription by selecting drug, dosage, quantity, and patient instructions 2
- The program checks that the selected drug is correct for the patient's medical condition, contraindications, for drug interactions with other current prescriptions and for correct patient instructions. Allergies are flagged
- Check patients health plan formulary for drug approval

- A bar code representing the drug brand name and strength is transferred to the Rx 3
- The physician then reviews Rx, prints and signs (if sending by computer fax etc – the signature is computer generated)
- To print: the PDA communicates wirelessly with the printer 11, 12
- To send to the pharmacy: the PDA sends the Rx to the PC. The PC electronically sends the Rx directly to the pharmacy via the Internet over a secured line. (Electronic Rx transmissions are permitted in most states, and will be soon allowed in Canada.)
- By using their PDA with WAN (wireless wide area network) capability, the physician is able to transmit, or fax an Rx to a pharmacy from remote locations
- The transmitted data is encrypted, complying with patient confidentiality issues
- To facilitate refills: the physician uses their PDA to call up the patients' file

#### HIGHLIGHTS

- Access to patient's file
- Printed Rx – prevents pharmacy errors caused by poor handwriting. Eliminates time consuming calls from pharmacists. Some physicians report saving 1 – 2 hours daily when using similar products
- Undertakes complete check of the Rx data
- Flags allergies
- Checks health plan formulary for drug authorization
- Choice of Rx format – printed in the physician's office and/or electronically sent to the pharmacy
- The Rx data is transferred to the patient file on office PC

- Speeds up the refill process. Rx data from patient file instantly available on PDA
- Prevents patient morbidity and mortality events
- Reduces the chance of lawsuits
- Reduces malpractice insurance premiums
- Drug safety notices etc, flagged on the physicians office computer, are transferred to the SafeRite System – continually upgrading the System's software
- Conforms to the 1st part of the "3 Part Action Plan" 2

IN THE PHARMACY      (Part Two)      SafeReader<sup>TM</sup>

HARDWARE

- SafeReader<sup>TM</sup> (combination bar code reader/printer) 12 provides an automated bar code comparison scan of the Rx 3 and drug's stock container. Prints Box four illustrated generic data 14
- SafeReader<sup>TM</sup> an indispensable pharmacy tool, which guarantees the drug taken from stock matches the Rx 3 in both selection and strength 12

SOFTWARE

- Compares Rx bar code 3 with bar code displayed on drug stock container 12
- Accepts generic substitutes to brand name drugs
- Transfers – Brand Name or Generic – scanned stock container's bar code to pharmacy working copy and patient Rx file

SEQUENCE OF USE

- Brand Name drug selection: To determine the drug taken from stock matches the Rx, the pharmacist places both the Rx and the drug stock container on the SafeReader™ unit 12
- SafeReader™ quickly performs a dual bar code scan – comparing drug name(s) and strength(s). Non matching data is immediately flagged 12
- SafeReader™ prints a validation (check) mark on the Rx 9. The pharmacist subsequently places his/her initials in the box provided 8
- SafeReader™ then transfers the drug's bar code to the pharmacy working copy and patient Rx file
- The Brand Name drug's bar code acts as a master bar code, and matches all generic substitute bar codes 3
- Generic drug selection: the generics' stock container is placed on SafeReader™ 12 and the generic container's bar code is scanned against the Rx's 3 bar code. SafeReader™ then transfers that [specific] generic drug's bar code\* to the pharmacy working copy and patient's Rx file. SafeReader prints a new Box Four information – containing the generic drug's data and illustration – onto an adhesive sticker, 15 which the pharmacist places over the original Box Four 6,14 (containing Brand Name drug data) on the Patient Checklist.
- On refills, the drug's [specific] bar code – from the patients' Rx file – is transferred to the pharmacy working copy
- The bar coded working copy is placed on SafeReader™ 12 – in the same manner as the original Rx 3 – and scanned against the drug's stock container – preventing refill mix-ups

\* The bar codes of allowable generic substitutions [to a given Brand Name drug] are not interchangeable. Only the originally dispensed generic drug's bar code will subsequently be accepted by SafeReader, thereby preventing mix-ups of [allowable] generic drugs when refilling an order.

At the time the generics' bar code is transferred to the pharmacy working copy and patient Rx file, the Brand Name's bar code data – imprinted on the Rx – is automatically invalidated by SafeReader, thereby, isolating the generics' [specific] bar code for future scanning checks.

Likewise, when a Brand Name drug is to be filled – and its bar code data transferred from the Rx to the pharmacy working copy and patient Rx File – the allowable generic substitution information – contained in the Brand Name's master bar code – is invalidated by SafeReader. Therefore, only SafeReader, assuring correct drug selection recognizes the bar code belonging to the Brand Name drug.

#### ADDITIONAL Rx BAR CODE(S)

Another bar code – containing patient ID etc. is added to the Rx – when scanned by SafeReader, this bar code opens up the (pharmacy) patient Rx file, preventing patient chart mix-ups and Rx/patient entry errors. This feature will facilitate further [scanned] safety checks. Other bar codes are added as necessary.

## GENERIC EQUIVALENT - ATTACHMENT

### SAFEREADER™ II – AN INTERMEDIATE SOLUTION

SafeReader™ II's software program, in essence, is the drug selection/bar coding portion of the physicians SafeRite™ software program. SafeReader™ II equips the pharmacist with a powerful safety tool. SafeReader™ II's program converts any Rx to a SafeRite™ [bar coded] type Rx. To accomplish this, the pharmacist enters the Rx drug name and strength into the pharmacy computer – the [SafeRite II] program converts this data to a bar code, which is printed together with drug name and strength, on an adhesive sticker 16, and affixed to the Rx. The bar coded Rx [attachment] and drug stock container are subsequently scanned by SafeReader™ 12 to assure correct drug and strength selection. The program then prints an abbreviated, illustrated Patient Checklist which accompanies the dispensed drug. 4

On the other hand, pharmacists who receive a SafeRite™ Rx 2, in a non SafeReader™ pharmacy, will benefit from SafeRite's™ printed Rx and Patient Check- List. 4

## PRINTING OPTIONS

The primary function of SafeReader™ is to provide a comparative bar code scan of the bar codes appearing on the Rx 3 and drug stock container. Printing is accomplished by incorporating a printer together with the bar code scanning mechanism into a single, stand-alone unit, or the printer is connected to the SafeReader unit.. The printer is calibrated to print a generic attachment 14 that affixes to Box Four of the Patient Check-List. Alternatively SafeReader™ functions solely as a bar code scanner, and the pharmacy printer undertakes printing the Box Four generic attachment. 14

The pharmacist separates the two parts of the Rx. 2, 4. The Patient Checklist 4 is attached to the dispensed drug vial etc.

The pharmacist, together with the patient, goes through the patient Checklist. 4

### HIGHLIGHTS

- Easy to read, printed Rx – prevents errors caused by poor handwriting – eliminates the need to call physician for clarification 2
- Eliminates the need to call physician regarding missing Rx data : ( ie quantity) 2
- An infallible method of preventing drug selection errors 3
- Patient diagnosis 10 prominently displayed on Rx- enables pharmacist to determine that the prescribed drug matches the patient's medical condition.(The MD may omit this information)
- Facilitates refills – scans [bar-coded] working copy with [bar coded] stock container.  
Prevents refill drug mix-ups
- Prevents patient morbidity and mortality events
- Reduces the chance of lawsuits
- Reduce malpractice premiums
- Conforms to the 2<sup>nd</sup> part of the “3 Part Action Plan” 3

### THE PATIENT (Part Three)

The patient is the ultimate beneficiary of the SafeRite System<sup>TM</sup>. Each feature of the Systems' technology is designed to prevent patient injury and death caused by medication errors. In doing so, the System confers many benefits to the other stakeholders in the Rx loop: namely the physician 2, pharmacist 3, and nurse. 17

### HARD COPY

- Patient Print- Out portion of the Rx (Patient Checklist) 4
- The Patient's Checklist accompanies the dispensed Rx

### SEQUENCE OF USE

- On receiving the dispensed drug, the patient – together with the pharmacist – follows the Checklist to compare the Patient Checklist data with the information printed on the prescription vial/container. 4
- Finally, the patient and pharmacist visually check that the dispensed medication matches the drug illustration in Box Four of the Checklist 6. In many cases the illustration is life-size.
- This third and last step of the 3 Part Action Plan – which takes only a few moments – is critical to the success of the error prevention program, and at the same time, conforms to [pharmacy] professional patient counseling requirements.

### HIGHLIGHTS

- Patient receives correct drug
- The System accesses pharmaceutical companies offering no cost/low cost drugs to patients encountering financial hardship.
- The patient is involved in a crucial step of the Rx loop
- Is guided through the checklist sequence 4
- Conforms to and completes all actions in the “3 Part Action Plan” 4
- Reduces patient morbidity and mortality events.

## IN THE HOSPITAL

### HARDWARE:

- PDA
- Printer
- SafeReader™
- Bedside Visual Display Kit 17

The hospital system requirements are much the same as those for the physician and pharmacy.

### SEQUENCE OF USE 16

- Doctor makes rounds, then using SafeRite™
- Selects and prints Rx. The Rx is either printed at the patient's bedside by using a handheld printer, or at the nurse's station (Drs. Desk)
- Copy of Patient Checklist (hospital version) placed in Bedside Visual Display 17 (BVD) \*
- 2<sup>nd</sup> copy of Rx and Patient Checklist placed in Patient Drug File (PDF) at nurses' station.\*
- The doctor transmits the Rx to the hospital pharmacy by fax, LAN or WAN - or submits a printed copy
- Rx data subsequently downloaded to patient's file on physician's office PC

\* When a generic substitution of the prescribed drug has taken place, the nurse attaches copies of the illustrated generic attachment 14 to Box Four of the Patient Checklist of the BVD 17 and PDF. Generic attachments are printed once only, and accompany the drug the first time it is dispensed to the patient.

## HIGHLIGHTS

In addition to:

- Physician Highlights
- Pharmacy Highlights
- Patient Highlights

Additional Hospital Highlights:

- Writing and printing the Rx at the patients bedside
- Patient Drug File (PDF). Enables check of Rx received at Nursing Station
- Bedside Visual Display 17 (BVD). Provides nurse with illustrated Rx information
- Infallible and inexpensive method of administering the right drug to the right patient

## IN THE HOSPITAL PHARMACY

- The pharmacist scans the Rx and drug stock container 12 – assuring correct drug and strength selection, prints generic sticker 14 – when necessary – and includes them with the patients drug. (Alternatively, a copy of the Patient Checklist accompanies the Rx, in which case, the pharmacist attaches the generic sticker 14 to Box Four of the Checklist, in the usual fashion (and an extra one for the PDF). The nurse peels off one of the stickers, attaches it to the PDF, then either exchanges the Patient Checklist for the one in the BVD 17, or peels off the remaining Box Four sticker, and attaches to the BVD 17 copy.) The hospital pharmacist may elect to convert a non SafeRite Rx to a bar coded Rx 16.

## NURSING STATION

- Dispensed drug received at nursing station
- If generic 14 - Box Four sticker attached to PDF

- Drug checked against PDF

WARD

- When administering the Rx to the patient in the ward, the nurse checks that the dispensed drug matches the [illustrated] Rx data included in the Patients Checklist, displayed in the BVD 17

Note: By following the unique and inexpensive BVD 17 drug administering protocol – which takes only a few moments – the nurse is assured that the right drug is given out to the right patient, and that the drug and drug strength complies with the written Rx order.

Patient data, such as condition/illness etc., is contained on the reverse side of the patients' nametag 17. Tags slip out easily for fast reference. In order to accommodate additional Rx's, additional display cards are hung beneath the original card 17. One card will contain recent medication history.

Routing information: ie Fl.5 Rm.123 Bd. C – is displayed on the Patient Checklist portion of the Rx, and accompanies the prescribed drug(s). The physician adds routing data at the time the Rx is written [on the PDA].

Option: The Rx/Checklist is folded back to back and placed in the clear plastic pouch of the BVD 17. Only the illustrated Checklist portion remains visible 17. To read the Rx, the doctor/nurse checks the reverse side of the BVD display card.

In order to facilitate writing the prescription at the patients' bedside, a custom designed case 18 will carry the PDA and printing unit, allowing hands free operation.